DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

94772d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-04-30

May 7, 2004

Pedro E. Gonzalez, President
One Way International, Inc.
8325 N.W. 30th Terrace
Miami, Florida 33122

Dear Mr. Gonzalez:

On February 23-25, 2004, the Food and Drug Administration (FDA) conducted an inspection of your seafood warehouse operation, located at the above address. The inspection was conducted to determine your firm's compliance with FDA's Seafood Hazard Analysis and Critical Control Point (HACCP) Regulations, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). Under 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan complying with that section, or otherwise to operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

During our inspection, the FDA investigator observed serious deviations from the Seafood (HACCP) Regulations in 21 CFR 123. These deviations cause your refrigerated ready-to-eat vacuum packaged smoked salmon products received and stored by your firm to be adulterated within the meaning of Section 402(a)(4) of the Act, 21 U.S.C. 342(a)(4). At the conclusion of the inspection, the investigator provided you with a list of Inspectional Observations (Form FDA 483), which presents her evaluation of your firm's performance regarding various aspects of the seafood HACCP requirements. The observations of concern to us are as follows:

> You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a), (b) and (c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may

cause a food to be unsafe for human consumption." However, your firm has not conducted a hazard analysis and no HACCP plan has been implemented for refrigerated ready-to-eat vacuum packaged smoked salmon received and stored by your firm to control the food safety hazard of *Clostridium botulinum* toxin formation that is reasonably likely to occur in refrigerated vacuum packaged products.

In addition, no calibration records were available for the thermometer used to determine the temperature of seafood products upon receipt. Documentation of calibration is required to be maintained by 21 CFR 123.8(d).

The deviations identified above are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products received, stored and distributed by your firm are in compliance with the Act and all requirements of the applicable federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated without further informal notice. Such actions may include the initiation of a seizure action against your products and/or an action to enjoin your firm from operating.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these deviations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, you may contact Mr. Walthall by telephone at (407) 475-4731.

Sincerely,

Emma R. Singleton
Director, Florida District